

### **REMARKS**

Applicants gratefully acknowledge the telephonic interviews granted by the Examiner to Applicants' counsel on December 3, 2003 and December 9, 2003. During the interviews, the Examiner indicated that the foregoing claim amendments would be allowable. Applicants note that the claim amendments are made solely in the interest of expediting the prosecution of this matter and not for reasons related to patentability. No prior art has been asserted against the claims.

In the final Office Action, claims 9-25, 32-35, 45-69 and 83 have been rejected. Claims 9-13, 18, 22, 25, 32, 45-46, 50-54, 58, 62, 65-66, 68-69 and 83 are amended herein, purely to further the prosecution of this matter. Claims 14-17, 19-21, 23, 24, 47-49, 55-57, 59-61, 63, and 64 are canceled without prejudice or disclaimer to the subject matter therein. Claims 1-8, 26-31, 36-44, and 70-82 are withdrawn pursuant to a restriction requirement.

The foregoing claim amendments are intended to clarify the inventive subject matter and thereby overcome the rejections under 35 U.S.C. § 112, first and second paragraphs and 35 U.S.C. § 101.

No new matter is submitted by these claim amendments and no new issues are raised by the claim amendments. Accordingly, applicants respectfully submit that the claim amendments and newly added claims should be entered.

Applicants will separately provide to the Examiner the references cited in the Information Disclosure Statement, but not received by the Examiner.

### **I. PATENTABLE UTILITY**

Claims 45-69 and 83 are rejected under 35 U.S.C. § 101 as lacking patentable utility and under 35 U.S.C. § 112, first paragraph. In particular, the Examiner rejects the recitation of the term "substances" in the claims because "the only disclosed 'substances' [in the specification] upon which claims might be based are contaminants,

substrates, or reagents, none of which comprise polypeptides having hexose oxidase activity." See Office Action, page 3. However, the Examiner correctly points out that "the specification discloses **compositions** that comprise the disclosed hexose oxidase . . ." Office Action, page 4.

Applicant's believe that the original language does not raise an issue of lack of patentable utility because a person of skill in the art would understand that the terms "substance" and "composition" may be used interchangeably and would be guided by the context in which the terms were used. Nevertheless, Applicants have amended the claims to replace the term "substance" with the term "composition" to further the prosecution of this matter. The foregoing amendments are intended merely to clarify the patentable utility of the claims and are not related to patentability of the claims.

In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 45-69 and 83 under 35 U.S.C. § 101 for lack of patentable utility and under 35 U.S.C. § 112, first paragraph.

## **II. THE WRITTEN DESCRIPTION REQUIREMENT IS SATISFIED**

Claims 9-25, 32-35 and 45-69 and 83 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

At the outset, applicants respectfully point out that the initial burden of establishing a basis for denying patentability of a claimed invention rests upon the Patent Office. See *In re Fine*, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). It is equally well established that the Patent Office bears the initial burden to establish a reasonable basis to question the written description provided in the specification for the invention defined in Applicants' claims. See *In re Wright*, 27 U.S.P.Q.2d 1510 (Fed. Cir. 1993).

Applicants respectfully traverse the Examiner's rejection for the following reasons. Applicants' full scope of claimed subject matter was described in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, even prior to the amendment of the claims herein. Applicants have amended their claims merely to clarify the subject matter of the claims and not for reasons related to patentability as is further explained below.

It is well established that a disclosure of the specification provides a description of the claimed subject matter if it reasonably conveys to persons skilled in the art that the inventor has possession of that subject matter at the time the application was filed. *See, e.g., Fujikawa v. Wattanasin*, 39 U.S.P.Q.2d 1895 (Fed. Cir. 1996) and *Vas-Cath, Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). Applicants respectfully submit that their specification, as filed, satisfied that standard because persons of ordinary skill in the art, familiar with applicants' specification, would clearly understand that they possessed the claimed subject matter. This is indicated, for example, by the Examiner's appreciation of the full scope of Applicants' claimed invention in the Office Action.

In the Office Action, the Examiner asserts that "the specification cannot be considered to exemplify or describe the preparation of generic polypeptides that need comprise no more specific structure than the hexadecapeptide of SEQ ID NO:3." See Office Action, page 5. However, as previously noted, under the current Written Description Guidelines of the U.S. Patent and Trademark Office (Patent Office), one way in which the written description requirement for a claimed genus may be satisfied is by disclosure of "relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus." 66 Fed. Reg. 1099, 1106 (2001). Here the claims specifically recite

structural characteristics (i.e., specific sequences, SEQ ID NO:3 in particular) and functional characteristics (i.e. hexose oxidase activity) and that this is coupled with a “disclosed correlation between function and structure” (the Specification clearly discloses a correlation between the recited structures and hexose oxidase activity, see Example 4, pages 64-72, Example 5, pages 73-75 and Example, 6, pages 75-77). Therefore, based upon the Patent Office’s own Guidelines, the specification satisfies the written description requirement.

Further, as also previously noted, one of the factors to be considered in determining if the written description requirement is satisfied is whether a representative number of species is disclosed in the specification. (See Guidelines, page 9). A representative number of species is disclosed if one skilled in the art would recognize that applicant possessed the necessary common attributes or features of the elements of the members of the genus in view of the species disclosed and claimed. *Id.* As clearly demonstrated by a review of the specification, applicants do indeed disclose such a representative number of species. See, for instance, Example 4, at pages 64-72, Example 5, pages 73-75 and Example, 6, pages 75-77.

In view of the foregoing comments, it is clear that the original claims satisfy the written description requirement. Nevertheless, as previously indicated, in the interest of advancing prosecution, applicants have amended their claims in accordance with the Examiner’s suggestions. Therefore, Applicants’ claimed subject matter continues to be described in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In view of the foregoing, a person skilled in the art would reasonably conclude that applicants were indeed in possession of the claimed invention. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

### **III. THE ENABLEMENT REQUIREMENT IS SATISFIED**

It is well established that the test for enablement is whether one of ordinary skill in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988); see also *United States v. Teletronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988).

In the Office Action, the Examiner rejects claims 9-25, 32-35, 45-69 and 83 as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention. In particular, the Examiner alleges that "there is no guidance or support in the specification for *de novo* design and preparation of generic polypeptides that have hexose oxidase activity and somewhere contain the specific hexadecapeptide having the amino acid sequence set forth in SEQ ID NO:3." Office Action, page 8. As noted in applicants' response to the previous Office Action, applicants respectfully submit that there is considerable direction and guidance in the specification, including specific examples, such that a person of skill in the art would be able to prepare the claimed subject matter without undue experimentation.

Although applicants believe that the original language of the claims is enabled by the specification, applicants have nevertheless amended the claims in the manner consistent with the Examiner's suggestions during the telephonic interview, in the interest of furthering the prosecution of this case. In particular, the claims recite the sequences of hexose oxidase (HOX) coding regions as clearly described in the specification.

In view of the foregoing, reconsideration and withdrawal of the rejections are respectfully requested.

#### **IV. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

Claims 45-69 and 83 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner alleges that "it is still unclear what is intended by the recitation of claim 45, '[a] substance having hexose oxidase activity' . . ." Office Action, page 9.

Applicants respectfully submit that the claims prior to their amendment herein were definite because persons skilled in the art would have been readily able to ascertain the scope of the claimed invention. As previously noted, applicants believe the terms substance and composition would be understood to be interchangeable and the meaning properly taken from the context of use. Nevertheless, applicants have amended their claims in an effort to expedite prosecution of the application.

In view of the foregoing, the amended claims continue to satisfy the definiteness requirements of 35 U.S.C. § 112, second paragraph. Accordingly, Applicants respectfully submit that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. § 112, second paragraph. The Examiner is welcomed to telephone the undersigned if any issues remain outstanding.

#### **REQUEST FOR ALLOWANCE**

For at least the reasons detailed above, applicants respectfully submit that all of the claims in the application are patentable. Favorable consideration, entry of this amendment, and issuance of a notice of allowance are respectfully requested.

If any issues remain, the Examiner is encouraged to contact applicants' representatives to resolve such issues in an expeditious manner, and place the application in condition for allowance.

In the event any fees are incurred upon the filing of these documents, please charge the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS

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